

## REMARKS

Claims 1-40 are pending and Applicants herewith amend independent claims 1, 17, and 28-33. No new claims are added and no claim is canceled.

Applicants respectfully request entry and favorable consideration of the amendments and remarks contained herein.

This Amendment after Final is submitted in an attempt to place the application in condition for allowance without raising additional issues or requiring additional search of the subject matter claimed. In the event that the Examiner does not issue a Notice of Allowance in response to the submission, Applicants respectfully request that the finality of the instant Office Action be reconsidered so that prosecution of the claimed subject matter may continue in due course.

### **Claim Rejections Under 35 U.S.C. §103**

**Claims 1, 2, 4-13, 15-18, 20-34 and 36-38 stand rejected under 35 U.S.C. §103(a) as unpatentable over the '428 patent to Obel et al. (Obel) in view of the '328 patent to Levine et al. (Levine).**

Applicants respectfully assert that suggestion or motivation to combine Obel with Levine is present in either reference. In fact, Levine only mentions the notion of neurological stimulation once; and even then only in the context of ***avoiding neurological stimulation***; to wit (from col. 31, lines 9-28):

It is also possible to program to the VDD mode in the presence of high atrial capture thresholds if the patient has high grade AV block, and only rarely or never needs AV pacing at the programmed base rate, thus forgoing atrial pacing in an effort to reduce battery current drain or ***avoid extracardiac muscle stimulation (such as the diaphragm via the phrenic nerve or direct stimulation of the pectoral muscle)***. An option may also be provided to disable the Preemptive tachyarrhythmia pacing algorithm when pacing in the VDD mode. (***emphasis added.***)

Since Levine actually can be seen to *teach away* from the notion of implementing neurological stimulation.

Furthermore, the independent claims have been herewith amended to more clearly indicate that the claimed invention relates to neuro-endocrinological system. In contrast, neither Obel nor Levine deals with such a system. The Examiner fails to cite any support for a difficult-to-parse statement that appears to be critical in forming the instant rejection of claims 1, 2, 4-13, 15-18, 20-34 and 36-38; namely, "neuro-endocrinological systems are recognized to be disease conditions that are often cluster [sic] in being that have compromised cardiac systems." Applicants respectfully request the Examiner to either restate the rejection or provide a basis in support of the proffered statement. In the absence of such action, Applicants assert that the rejection fails to meet the minimum threshold for a *prima facie* obviousness rejection.

Accordingly, Applicants request that the Examiner withdrawn the rejection of claims 1, 2, 4-13, 15-18, 20-34 and 36-38 based upon Obel and Levine.

**Claims 1, 2, 4-13, 15-18, 20-34 and 36-38 stand rejected under 35 U.S.C. §102(b) as anticipated by Obel in view of the '098 patent to Bennett et al. (Bennett).**

The Examiner has essentially restated the rejection based on Obel and Levine by substituting Bennett in lieu of Levine. However, Applicants respectfully point out that Bennett is devoid of any disclosure regarding overdrive pacing; and, in fact the typical effect of the post-extrasystolic potentiation (PESP) therapy described and claimed in Bennett is to **halve the heart rate** (relative to a prior non PESP therapy delivery heart rate). In addition, Bennett is devoid of any mention or suggestion regarding neuro-endocrinological system imbalance(s).

Thus, not only is Bennett devoid of any support for adding overdrive pacing it is fact teaches away from increasing heart rates via pacing therapy delivery. Beside not providing any teaching or suggestion regarding imbalance of the neuro-endocrinological system and teaching away from the claimed

subject matter, the primary references relied upon by the Examiner also fail to provide any basis for one of skill in the art to provide the claimed subject matter.

Accordingly, Applicants request that the Examiner withdrawn the rejection of claims 1, 2, 4-13, 15-18, 20-34 and 36-38 based upon Obel and Bennett.

**Claims 3, 19, and 39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Obel in view of Levine in further view of the '187 patent to Adams (Adams).**

The remarks provided above regarding the proposed combination of Obel and Levine are incorporated as if set forth herein. That is, in essence, because Levine teaches away from providing neurostimulation in conjunction with providing a pacing therapy, the combination of Obel and Levine fails at achieving even the initial threshold for providing a *prima facie* obviousness rejection.

In addition, the rejected claims depend directly or indirectly from one of the independent claims and neither Obel nor Adams includes any disclosure or teaching regarding PESP or overdrive pacing therapy delivery. According, the combination of Obel, Levine, and Adams cannot form a *prima facie* obviousness rejection and should be withdrawn.

**Claims 14, 35, and 40 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Obel in view of Levine in further view of the '377 patent to Sweeney et al. (Sweeney).**

The remarks provided above regarding the proposed combination of Obel and Levine are incorporated as if set forth herein. That is, in essence, because Levine teaches away from providing neurostimulation in conjunction with providing a pacing therapy, the combination of Obel and Levine fails at achieving even the initial threshold for providing a *prima facie* obviousness rejection.

The rejected claims depend directly or indirectly from one of the independent claims and neither Obel nor Sweeney includes any disclosure or teaching regarding PESP or overdrive pacing therapy delivery. According, the combination of Obel and Sweeney cannot form a *prima facie* obviousness rejection and should be withdrawn.

Furthermore, because the independent claims each recite limitations regarding improving imbalance(s) of the neuro-endocrinological system and the fact that the references applied (alone and in combination) fail to include, teach, disclose, inform, or motivate those of skill in the art vis-à-vis the claimed subject matter, the rejections fail to render same *prima facie* obvious. In contrast, none of the cited and applied references provides a therapy regimen for balancing the neuro-endocrinological system they cannot support rejection of the claimed invention.

In addition, Applicants respectfully point out that a patient suffering from mechanical inefficiency does not necessarily suffer from ventricular dysfunction and for that reason, among others, some of the amendments herewith have been recorded.

### **Conclusion**

Applicants respectfully suggest that all pending claims are in condition for allowance and the Examiner is earnestly solicited to issue a Notice of Allowance in due course.

Applicants repeat the request for reconsideration of the finality of the instant Office Action so that prosecution on the merits can proceed and so the Examiner can provide support for the difficult-to-parse language employed in discussing Obel and Levine in rejecting claims 1, 2, 4-13, 15-18, 20-34 and 36-38.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Respectfully submitted,

Date: May 15, 2006

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